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a means for detecting the binding moiety bound to the breast cancer-associated protein; and  
a reference sample.

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### REMARKS

Upon entry of this paper, claims 1-8, 21-40 and 56-62 are cancelled without prejudice to Applicants' right to pursue their subject matter in this application or in a related application. Claims 9 and 15 are rewritten in independent form and have been amended to recite that the protein is about 28 kD, binds in the presence of 50 mM sodium phosphate, pH 7.0, to an anion exchange resin comprising quarternary ammonium groups, and elutes from the resin in the presence of 50 mM sodium chloride in 50 mM sodium phosphate, pH 7.0. Support for the amendment to claims 9 and 15 can be found throughout the application as filed and at least at pages 34-37. Claim 41 has been rewritten in independent form and amended to recite a protein comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1-23. Support for the amendment to claim 41 can be found throughout the application as filed, and at least in the sequence listing and in originally-filed claim 43. Applicants enclose a marked-up copy of the amended claims in accordance with 37 C.F.R. § 1.121(c)(1)(ii). Applicants submit no new matter has been added by these amendments.

Claims 9-20 and 41-55 are pending.

#### ***Requirement to restrict***

The Office Action alleges that the previously pending claims defined eight patentably distinct inventions, including: Group I, claims 1-8; Group II, claims 9-14 and 43-47; Group III, claims 15-20, 41, 42, and 48-55; Group IV, claims 21-24; Group V, claims 25 and 26; Group VI, claims 27-31; Group VII, claims 32 and 33; and Group VIII, claims 34-40 and 56-62. Applicants have cancelled without prejudice all claims from

Groups I, IV, V, VI, VII, and VIII, obviating the restriction requirement with respect to those claims. Thus, only claims corresponding to Groups II and III remain.

Applicants provisionally elect, with traverse, Group II, including claims 9-14 and 43-47.

Applicants respectfully traverse the restriction requirement as applied to Groups II and III. “If the search and examination of [both sets of claims] can be made without serious burden, the examiner must examine [them] on the merits, even though [the] claims [are] to independent or distinct inventions” (MPEP § 803.01). As defined by the Office action, Group II relates to a method of diagnosing cancer comprising detecting the presence of a polypeptide, and Group III relates to a method of diagnosing cancer comprising contacting a sample with a binding moiety. Applicants submit that one method of detecting the presence of a polypeptide involves the use of a binding moiety, for example, an antibody. Accordingly, Applicants submit that a search and examination of the invention of Group II (detection of a polypeptide) includes a search of art relevant to Group III (contacting a sample with a binding moiety). Applicants therefore request reconsideration of the restriction requirement as applied to Groups II and III, and request rejoinder of the claims of Groups II and III into a single Group.

***Election of species***

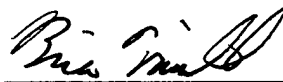
To the extent that Applicants elect Group II, III, or VIII, the Office action also requires election of one polypeptide sequence for use in the elected method claims. Applicants provisionally elect, with traverse, the sequence of SEQ ID NO:1. Applicants note that SEQ ID NO:1-4 are each subsequences of SEQ ID NO:5, U2 snRNP B”.

Applicants further submit that all pending claims are readable on the provisionally elected species. Applicants understand that upon allowance of generic claims corresponding to the elected species, Applicants may claim additional species as provided by 37 C.F.R. § 1.141.

### CONCLUSION

Upon entry of this paper, claims 9, 15 and 41 are amended and claims 1-8, 21-40 and 56-62 are cancelled. Claims 9-20 and 41-55 will remain pending. Group II and SEQ ID NO:1 are hereby provisionally elected with traverse. The Examiner is invited to contact the undersigned to discuss any outstanding issues. Early favorable action is respectfully requested.

Respectfully submitted,



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MARKED-UP COPY OF AMENDED CLAIMS

9. (Amended) A method of diagnosing cancer in an individual comprising detecting in a sample isolated from the individual the presence of [the polypeptide of claim 1] a cancer-associated protein of about 28 kD that

(i) binds in the presence of 50 mM sodium phosphate, pH 7.0, to an anion exchange resin comprising quaternary ammonium groups and

(ii) elutes from the resin in the presence of 50 mM sodium chloride in 50 mM sodium phosphate, pH 7.0, [which if present] wherein the cancer-associated protein is indicative of cancer in the individual.

15. (Amended) A method of diagnosing cancer in an individual, the method comprising the steps of:

(a) contacting a sample from the individual with a binding moiety that binds specifically to a cancer-associated protein to produce a binding moiety-cancer-associated protein complex, wherein the binding moiety binds specifically to [the polypeptide of claim 1] a cancer-associated protein of about 28 kD that (i) binds in the presence of 50 mM sodium phosphate, pH 7.0, to an anion exchange resin comprising quaternary ammonium groups and (ii) elutes from the resin in the presence of 50 mM sodium chloride in 50 mM sodium phosphate, pH 7.0; and

(b) detecting the [presence of the] complex, which [if present] is indicative of the presence of cancer in the individual.

41. (Amended) A kit for detecting the presence of breast cancer or for evaluating the efficacy of a therapeutic treatment of a breast cancer, the kit comprising in combination:

a receptacle for receiving a tissue or body fluid sample from a mammal;

a binding moiety which binds specifically to [the] a breast cancer-associated protein [of claim 1] comprising an amino acid sequence selected from the group

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consisting of SEQ ID NO: 1; SEQ ID NO: 2; SEQ ID NO: 3; SEQ ID NO: 4; SEQ ID NO: 5; SEQ ID NO:6; SEQ ID NO:7; SEQ ID NO:8; SEQ ID NO:9; SEQ ID NO:10; SEQ ID NO:11; SEQ ID NO:12; SEQ ID NO:13; SEQ ID NO:14; SEQ ID NO:15; SEQ ID NO:16; SEQ ID NO:17; SEQ ID NO:18; SEQ ID NO:19; SEQ ID NO:20; SEQ ID NO:21, SEQ ID NO:22; and SEQ ID NO:23;

a means for detecting the binding moiety bound to the breast cancer-associated protein; and

a reference sample.

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